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HDP/SB/21 based on PTO/SB/21 (08-00)

 <b>TRANSMITTAL FORM</b> (to be used for all correspondence after initial filing)	<b>Application Number</b>	10/643,674
	<b>Filing Date</b>	August 19, 2003
	<b>First Named Inventor</b>	Hyon et al.
	<b>Group Art Unit</b>	
	<b>Examiner Name</b>	
<b>Number of Pages in This Submission</b>	<b>Attorney Docket Number</b>	1736-000001/REB

ENCLOSURES (check all that apply)		
<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment / Response <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input checked="" type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Response to Missing Parts/Incomplete Application <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Assignment Papers (for an Application) <input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____	<input type="checkbox"/> After Allowance Communication to Group <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): <p style="text-align: center;"><b>Form 1449; Return postcard</b></p>
<b>Remarks</b>		<b>The Commissioner is hereby authorized to charge any additional fees that may be required under 37 CFR 1.16 or 1.17 to Deposit Account No. 08-0750. A duplicate copy of this sheet is enclosed.</b>

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT			
<b>Firm or Individual name</b>	Harpess, Dickey & Pierce, P.L.C.	<b>Attorney Name</b>	Reg. No.
<b>Signature</b>	David L. Suter		30,692
<b>Date</b>	November 19, 2003		

CERTIFICATE OF MAILING/TRANSMISSION			
I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Director of the U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450, or facsimile transmitted to the U.S. Patent and Trademark Office on the date indicated below.			
<b>Typed or printed name</b>	David L. Suter		
<b>Signature</b>		<b>Date</b>	November 19, 2003



**PATENT**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.: 10/643,674  
Filing Date: August 19, 2003  
Applicant: Hyon et al.  
Title: Ultra High Molecular Weight Polyethylene Molded Article For Artificial Joints and Method of Preparing The Same  
Attorney Docket: 1736-000001/REB

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Director of the United States Patent and Trademark Office  
P.O. Box 1450  
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT**

Sir:

Pursuant to 37 C.F.R. §§ 1.56, 1.97 and 1.98, Applicant hereby submits an Information Disclosure Statement for consideration by the Examiner.

I. LIST OF PATENTS, PUBLICATIONS, AND OTHER INFORMATION

The patents, publications and other information requested to be considered by the Office (except unpublished U.S. patent applications) are listed on Form 1449 attached hereto.

II. COPIES

A. \_\_\_\_\_ Submitted herewith is a legible copy of (i) each U.S. patent application publication and U.S. and foreign patent; (ii) each publication or that portion which caused it to be listed; (iii) for each cited pending U.S. application, the application specification including the claims, and any drawing of the application which caused it to be listed including the claims directed to that portion; and (iv) all other information or that portion which caused it to be listed.

B. X Any patents, publications or other information which are listed on Form 1449 or on the copies of PTO-892, but which are not enclosed herewith, were previously cited by or submitted to the PTO in one of the following applications which has been relied upon for an earlier filing date under 35 U.S.C. § 120:

U.S. Serial Number  
10/141,374

U.S. Filing Date  
May 8, 2002

C. X Because the present application was/is being filed after June 30, 2003, no copies of the U.S. patents or U.S. patent application publications which are listed on the attached Form 1449 are enclosed pursuant to the waiver of 37 C.F.R. § 1.98(a)(2)(i). Any foreign patent documents or non-patent literature listed on the attached Form 1449 are enclosed herewith.

D. \_\_\_\_ This is a PCT application in the entry of the National Phase in the United States. A copy of the International Search Report is attached for the Examiner's information. The documents listed on the International Search Report are listed on the attached Form-1449 for consideration by the Examiner and for listing on any patent resulting from this application. Since the International Search Report was from the US, EPO, or JPO search authorities, copies of these references should have been supplied to the USPTO under the trilateral agreement and are believed to be in the file of the above-identified application. (MPEP 1893.03(g))

III. CONCISE EXPLANATION OF THE RELEVANCE (check at least one box)

A. X Except as may be indicated below in (B), all of the patents, publications or other information are in the English language (concise explanation not required).

B. \_\_\_\_ A concise explanation of the relevance of each patent, publication or other information listed that is not in the English language is as follows (see 37 C.F.R. § 1.98(a)(3)):

1. \_\_\_\_ See the attached foreign patent office communication from a counterpart foreign application:
2. \_\_\_\_ English translations are provided:
3. \_\_\_\_ Other:

C. \_\_\_\_ The following additional information is provided for the Examiner's consideration.

IV. CROSS REFERENCE TO RELATED APPLICATION(S)

A. \_\_\_\_ The Examiner is advised that the following co-pending application(s) contain(s) subject matter that may be related to the present application. By bringing this(these) application(s) to the Examiner's attention, Applicant(s) does(do) not waive the confidentiality provisions of 35 U.S.C. § 122.

Serial No.

Filing Date

Art Unit

V. THIS IDS IS BEING FILED UNDER

A. X 37 C.F.R. § 1.97(b): (check only one box)

1. \_\_\_\_ within three months of the filing date of a national application other than a continued prosecution application under § 1.53(d) (37 C.F.R. § 1.97(b)(1)). No fee or certification is required.

2. \_\_\_\_ within three months of the date of entry of the national stage as set forth in §1.491 in an international application (37 C.F.R. § 1.97(b)(2)). No fee or certification is required.

3. X before the mailing of a first Office Action on the merits (37 C.F.R. § 1.97(b)(3)). No fee or certification is required. In the event that a first Office Action on the merits has been issued, please consider this IDS under 37 C.F.R. § 1.97(c) and see the certification under 37 C.F.R. § 1.97(e) below; or, if no certification has been made, charge our deposit account a fee in the amount of \$180.00 as required by 37 C.F.R. § 1.17(p).

4. \_\_\_\_ before the mailing of a first Office Action after the filing of a request for continued examination under 37 C.F.R. § 1.114. No fee or certification is required.

B. \_\_\_\_ **37 C.F.R. § 1.97(c):** (check only one box)

before the mailing date of either any Final Office Action under 37 C.F.R. § 1.113, a Notice of Allowance under 37 C.F.R. § 1.311, or an action that otherwise closes prosecution.

1. \_\_\_\_ No certification; therefore, a fee in the amount of \$180.00 is required by 37 C.F.R. § 1.17(p).

2. \_\_\_\_ See the certification below. No fee is required.

C. \_\_\_\_ **37 C.F.R. § 1.97(d):**

after the mailing date of either a Final Office Action under 37 C.F.R. § 1.113 or a Notice of Allowance under 37 C.F.R. § 1.311, yet on or before payment of the issue fee.

1. \_\_\_\_ See the certification below. A fee in the amount of \$180.00 is required by 37 C.F.R. § 1.17(p).

VI. **CERTIFICATION UNDER 37 C.F.R. § 1.97(e):** (check only one box)

The undersigned hereby certifies that:

A. \_\_\_\_ each item of information contained in this IDS was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS (See 37 C.F.R. § 1.97(e)(1)). See further statement under 37 C.F.R. § 1.704(d) below in section VII, if applicable; or

B. \_\_\_\_ no item of information contained in this IDS was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in this

IDS was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this IDS (See 37 C.F.R. § 1.97(e)(2)).

C. \_\_\_\_ Some of the items of information were first cited in a communication from a foreign patent office. As to this information, the undersigned hereby certifies that each item of information contained in this IDS was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS. As to the remaining information, the undersigned hereby certifies that no item of this remaining information contained in this IDS was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in this IDS was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this IDS.

VII. STATEMENT UNDER 37 CFR 1.704(d)

The undersigned hereby states that:

\_\_\_\_ each item of information contained in this IDS was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in 37 C.F.R. § 1.56(c) more than thirty days prior to the filing of this IDS.

VIII. PAYMENT OF FEES (check only one box)

A. \_\_\_\_ A check in the amount of \$180.00 is enclosed for the above-identified fee.

B. \_\_\_\_ Please charge Deposit Account No. 08-0750 in the amount of \$180.00 for the above-indicated fee. A duplicate copy of this paper is attached.


The above references are being cited only in the interest of candor and without any admission that they constitute statutory prior art, contain matter which anticipates the invention, or which would render the same obvious, either singly or in combination, to a person of ordinary skill in the art. Furthermore, this Information Disclosure Statement shall not be construed as a representation that a search has been made.

If it is determined that this IDS has been filed under the wrong rule, the PTO is requested to consider this IDS under the proper rule (with a petition if necessary) and charge the appropriate fee to Deposit Account No. 08-0750.

Please charge any additional fees or credit any overpayment pursuant to 37 C.F.R. § 1.16 or § 1.17 to Deposit Account No. 08-0750.

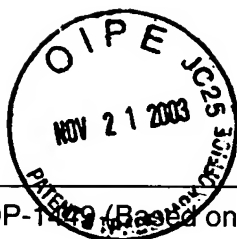
Respectfully submitted,

Dated: 19 November 2003

By:   
David L. Suter  
Reg. No. 30,692

HARNESS, DICKY & PIERCE, P.L.C.  
P.O. Box 828  
Bloomfield Hills, Michigan 48303  
(248) 641-1600

DLS/akb



FORM HDP-1449 (Based on Form PTO-1449)

**PATENT AND TRADEMARK OFFICE**  
**INFORMATION DISCLOSURE CITATION**  
(Use several sheets if necessary)

Sheet 1 of 6

ATTORNEY DOCKET No.

SERIAL No.

1736-000001/REB

10/643,674

APPLICANT

Hyon et al.

FILING DATE

GROUP

August 19, 2003

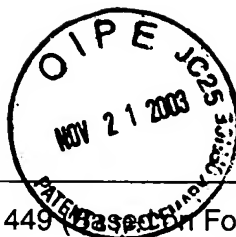
**U.S. PATENT DOCUMENTS**

Ref. Desig.	Examiner's Initials	Document Number	Date	Name	Class/ Subclass	(If appropriate) Filing Date
1.		3,886,056*	05/27/1975	Kitamaru et al.		
2.		4,224,696*	09/30/1980	Murray et al.		
3.		4,587,163*	05/6/1986	Zachariades		
4.		4,636,340*	01/13/1987	Itaba et al.		
5.		4,655,769*	4/7/1987	Zachariades		
6.		4,747,990*	5/31/1988	Gaussens et al.		
7.		5,030,402*	7/9/1991	Zachariades		
8.		5,030,487*	7/9/1991	Rosenzweig		
9.		5,066,755*	11/19/1991	Lemstra		
10.		5,130,376*	7/14/1992	Shih		
11.		5,276,079*	1/4/1994	Duan et al.		
12.		5,358,529*	10/25/1994	Davidson		
13.		5,405,393*	4/11/1995	Falkenstrom		
14.		5,428,079*	6/27/1995	Bastiaansen et al.		
15.		5,728,748*	3/17/1998	Sun et al.		
16.		2,948,666	8/9/1960	Lawton		
17.		3,362,897	1/9/1968	Lawton		
18.		3,956,253	5/11/1976	Braun		
19.		4,055,862	11/1/1977	Farling		
20.		4,171,338	10/16/1979	Mason		
21.		4,281,420	8/4/1981	Raab		

Examiner:

Date Considered:

EXAMINER: Please initial if citation considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



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Sheet 2 of 6

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**U.S. PATENT DOCUMENTS**

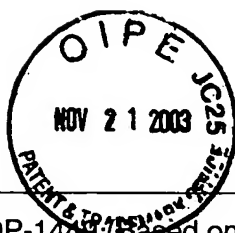
Ref. Desig.	Examiner's Initials	Document Number	Date	Name	Class/ Subclass	(If appropriate) Filing Date
22.		4,582,656	4/15/1986	Hoffman		
23.		5,200,439	4/6/1993	Asanuma		
24.		5,210,130	5/11/1993	Howard, Jr.		
25.		5,414,049	5/9/1995	Sun et al.		
26.		5,439,949	8/8/1995	Lucas et al.		
27.		5,449,745	9/12/1995	Sun et al.		
28.		5,505,900	4/9/1996	Suwanda et al.		
29.		5,543,471	8/6/1996	Sun et al.		
30.		5,552,104	9/3/1996	DeNicola, Jr. et al.		
31.		5,577,368	11/26/1996	Hamilton et al.		
32.		5,650,485	7/22/1997	Sun et al.		
33.		5,879,400	3/9/1999	Merrill et al.		
34.		6,017,975	1/25/2000	Saum et al.		
35.		6,165,220	12/26/2000	McKellop et al.		
36.		6,174,934	1/16/2001	Sun et al.		
37.		6,184,265 B1	2/6/2001	Hamilton et al.		
38.		6,228,900 B1	5/8/2001	Shen et al.		
39.		6,281,264 B1	8/28/2001	Salovey et al.		
40.		6,365,089 B1	4/2/2002	Krebs et al.		
41.		6,458,727 B1	10/1/2002	Jones et al.		

Examiner:

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Sheet 3 of 6

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GROUP

August 19, 2003

**U.S. PATENT DOCUMENTS**

Ref. Desig.	Examiner's Initials	Document Number	Date	Name	Class/ Subclass	(If appropriate) Filing Date
42.		2002/0125614 A1	09/12/02	King et al.		
43.		2002/0037944 A1	03/28/02	Shen et al.		
44.		2003/0119935 A1	06/26/03	Merrill et al.		
45.		6,494,917 B1	12/17/02	McKellop et al.		
46.		6,355,215 B1	03/12/02	Poggie et al.		
47.		2002/0107300 A1	08/08/02	Saum et al.		
48.		2002/0161438 A1	10/31/02	Scott et al.		
49.		2003/0045603 A1	03/06/03	Salovey et al.		
50.		2003/0130743 A1	07/10/03	Scott et al.		
51.		2003/0149125 A1	08/07/03	Muratoglu et al.		
52.		6,048,480	04/11/00	Doyle		
53.		6,146,426	11/14/00	Doyle		

**FOREIGN PATENT DOCUMENTS**

Ref. Desig.	Examiner's Initials	Document Number	Date	Country	Class/ Subclass	Translation Yes	No
1.		JP 57-211347	12/25/1982	Japan		X	
2.		JP 91 22222	5/13/1997	Japan		Abstract	
3.		WO 95/06148*	3/2/1995	PCT			
4.		WO 98/01085	1/15/1998	PCT			
5.		JP 62 243634	10/24/1987	Japan		Abstract	

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Sheet 4 of 6

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Ref. Desig.	Examiner's Initials	Document Number	Date	Country	Class/ Subclass	Translation Yes	No
6.		JP 4-198201	7/17/1992	Japan		Abstract	
7.		EP 0 729 981 A1	9/4/1996	Europe			
8.		JP 5-507748	11/4/1993	Japan		Abstract	
9.		JP 2-175137	7/6/1990	Japan		Abstract	

**OTHER DOCUMENTS (including Author, Title, Date, Pertinent Pages, etc.)**

Ref. Desig.	Examiner's Initials	
1.		Choudhury et al., "The effects of irradiation and ageing on the abrasive wear resistance of ultra high molecular weight polyethylene," Wear 203-204 (1997), pp. 335-340.
2.		International Search Report, PCT/US97/11947 - included in WO 98/01085.
3.		Kang et al., "The Radiation Chemistry of Polyethylene. IX. Temperature Coefficient of Cross-Linking and Other Effects," Journal of the American Chemical Society, Vol. 89:9, April 26, 1967, pp. 1980-1986.
4.		Kitamura, R. et al., "The Properties of Transparent Film Made from Linear Polyethylene By Irradiation Cross-Linking," Macromolecules, vol. 6, 1973, pp. 337-343.*
5.		Kitamura, R. et al., Structure and Properties of Lightly Crosslinked Crystalline Polymers Crystallized or Processed under Molecular Orientation, Journal of Polymer Science: Macromolecular Reviews, vol. 14, 1979, pp. 207-264.*
6.		Kitamura, R. et al., "Size and Orientation of Crystallites in Lightly Cross-linked Polyethylene, Crystallized from the Melt Under Uniaxial Compression," Die Makromolekulare Chemie, vol. 175, 1974, pp. 255-275.*
7.		O'Neill et al., "The distribution of oxidation products in irradiated ultra-high molecular weight polyethylene," Polymer Degradation and Stability (Feb. 1995), pp. 239-244.

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Sheet 5 of 6

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Hyon et al.

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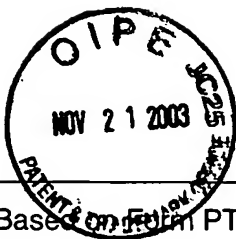
**OTHER DOCUMENTS (including Author, Title, Date, Pertinent Pages, etc.)**

Ref. Desig.	Examiner's Initials	
8.		Oonishi et al., "Effect of cross-linkage by gamma radiation in heavy doses to low wear polyethylene in total hip prostheses," Journal of Materials Science: Materials in Medicine 7 (1996), pp. 753-763.
9.		Oonishi et al., "The optimum dose of gamma radiation-heavy doses to low wear polyethylene in total hip prostheses," Journal of Materials Science: Materials in Medicine 8 (1997), pp. 11-18.
10.		Polymer Society, Polymer Functional Material Series-Medical Treatment Functional Material, Vol. 9, November 20, 1990, pp. 165-166.
11.		Polymer Society, Polymer New Material One Point-Medical Polymer Material, Vol. 20, February 20, 1989, pp. 45-46.
12.		Premnath, "Gamma sterilization of UHMWPE articular implants: an analysis of the oxidation problem," Biomaterials, Vol. 17 No. 18 (1996), pp. 1741-1753.
13.		Sun et al., "Development of an Accelerated Aging Method For Evaluation of Long-term Irradiation Effects on UHMWPE Implants," (1996), Howmedia Inc., Pfizer Hospital Products Group, pp. 969-970.
14.		Supplementary European Search Report, EP 95931434, December 28, 1998 - corresponds to EP 0729981.
15.		The American Academy of Orthopaedic Surgeons, "Polyethylene: The Past, Present and Future," 1999 Annual Meeting - Scientific Program, February 5, 1999, <a href="http://www.aaos.org/wordhtml/anmett99/sciprog/g.htm">www.aaos.org/wordhtml/anmett99/sciprog/g.htm</a> (20 pages).
16.		The American Academy of Orthopaedic Surgeons, "Researchers get awards for orthopaedic research," News Release, March 19, 1998, <a href="http://www.aaos.org/wordhtml/press/98press/kappa.htm">www.aaos.org/wordhtml/press/98press/kappa.htm</a> (4 pages).
17.		The American Academy of Orthopaedic Surgeons, "Researchers to get Kappa Delta awards for achievements," Academy News, March 19, 1998, <a href="http://www.aaos.org/wordhtml/98news/kappa.htm">www.aaos.org/wordhtml/98news/kappa.htm</a> (3 pages).
18.		Tribology Laboratory information sheet and curriculum vitae for Drs. McKellop and Shen, <a href="http://www.orthohospital.org/research/Tribology%20Lab">www.orthohospital.org/research/Tribology Lab</a> (5 pages).

Examiner:

Date Considered:

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Sheet 6 of 6

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August 19, 2003

**OTHER DOCUMENTS (including Author, Title, Date, Pertinent Pages, etc.)**

Ref. Desig.	Examiner's Initials	
19.		Wilson et al., "Proton Modification of Ultra High Molecular Weight Polyethylene to Promote Crosslinking for Enhanced Chemical and Physical Properties," Materials Research Society Symposium Proceedings, Vol. 396 (1995), pp. 311-316.

\* Indicates previously cited in original U.S. Patent 6,168,626.

Examiner:

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EXAMINER: Please initial if citation considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.